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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/438,104

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ASGEIR SAEBO

CONLINCO-040

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MEDLEN & CARROLL, LLP
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EXAMINER

ZHANG, NANCY L

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/438,104

Applicant(s)

SAEBO ET AL.

Examiner

Nancy L. Zhang

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Prosecution Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/2006 has been entered.

Applicant's Terminal Disclaimer, filed on 8/24/2006, has overcome the obviousness-type provisional double patenting rejection over copending application 09/132,593.

Claims 7-24 are pending.

Claim Objections

Claims 9, 12, 15, 18, 21 and 24 are objected to because of the following informalities: The use Markush group is improper. The components in a Markush group should be singular, linked by commas and the conjunction word "and" should be used to link the last two components in the Markush group.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "being characterized by" renders the claims indefinite because this recitation is directed to a feature that is not necessarily present and thereby renders the claims indefinite. This rejection can be overcome by re-phrasing the claims to avoid using the phrase "characterized by". For example, applicant may wish to recite claim 1 as "An isomerized conjugated linoleic acid composition comprising c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid wherein the total amount of c9,t11-octadecadienoic and c10,t12-octadecadienoic acid is at least 50% and the total amount of the isomers of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid is less than one percent.

The term "peak area percentage" in the claims is a relative term which renders the claim indefinite. The term "peak area percentage" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention because it is unclear what the limitation is by the recitation of "peak area percentage".

The recitation of "comprising at least 50% c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid" renders the claims indefinite because there could be two different interpretations for this recitation as follows:

The isomerized conjugated linoleic acid composition comprising c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid where the amount of c9,t11-octadecadienoic acid is at least 50% and there is no limit for the amount of c10,t12-octadecadienoic acid; or

The isomerized conjugated linoleic acid composition comprising c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid where the total amount of c9,t11-octadecadienoic and c10,t12-octadecadienoic acid together is at least 50%.

For examination purposes, the latter interpretation is used.

The recitation of "including less than one percent 11,13-octadecadienoic and 8,11-octadecadienoic acid isomers expressed as peak area percentage" renders the claims indefinite because there could be two different interpretations for this recitation as follows:

The isomerized conjugated linoleic acid composition is characterized in including less than one percent of 11,13-octadecadienoic acid and including the 8,10-octadecadienoic acid isomers expressed as peak area percentage; or

The isomerized conjugated linoleic acid composition is characterized in including the isomers of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid where the total amount of the isomers of 11,13-octadecadienoic acid and 8,10-octadecadienoic acid is less than one percent which is the peak area percentage.

For examination purposes, the latter interpretation is used.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-9, 11-12, 14-15, 17-18, 20-21 and 23-24 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of claims 8-9, 11-12, 14-15, 17-18, 20-21 and 23-24 are directed to a composition of isomerized conjugated linoleic acid comprising c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid where the total amount of c9,t11-octadecadienoic and c10,t12-octadecadienoic acid together is at least 50% wherein said conjugated linoleic acid composition is an ester. Claims 9, 12, 15, 18, 21 and 24 are directed to esters selected from the group consisting of methyl esters, ethyl esters, triglycerides.

The recitation of the claims encompasses a broad range of compounds without any structural limitation other than the requirements of a chemical bond for an ester. An ester of a compound only defines a chemical bond in the compound and therefore encompasses an unlimited range of compounds. Furthermore, the recitation of claims 9, 12, 15, 18, 21 and 24 encompasses mixtures of the esters. The specification only

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provides in one situation where the free fatty acids from the isomerization of Safflower Oil are converted to methylesters for Gas Chromatography analysis. The specification does not provide any description for the esters of octadecadienoic acid or mixtures of the esters. No support or working example of the esters of octadecadienoic acid is provided in the specification for the claimed composition. No structure is defined other than the chemical bond of ester. No guidance is established as to how to screen for the compound of an ester of the octadecadienoic acid or a mixture of the esters. The disclosure does not meet the written description provision of 35 USC § 112, 1st Paragraph. The specification provides insufficient written description to support the genus encompassed by the claims to include an ester of the octadecadienoic acid.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is not claimed.” (See page 1117). The specification does not “clearly allow persons of ordinary skilled in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

In the instant case, a skilled artisan cannot envision the detailed chemical structure of an ester of the octadecadienoic acid or mixtures of the esters of the octadecadienoic acid. Adequate written description requires more than a mere statement that it is part of the invention and reference to potential compounds. The chemical itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)

and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F. 2d 1008, 1012, 10 USPQ2D 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2D at 1966.

Therefore, claims 8-9, 11-12, 14-15, 17-18, 20-21 and 23-24 do not meet the written description provision of 35 USC § 112, 1st Paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision (see page 1115).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional obviousness-type double patenting rejection of claims 8, 9, 11, 12, 14, 15, 17, 18, 20, 21 and 22 over claims 1-3 of copending Application No. 10/623,825 is maintained and repeated. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and the copending Application teach esters of and triglycerides of octadecadienoic acids having content of c9, t11- and t10, c12-octadecadienoic acid greater than 50% wherein the content of 8,10- and 11,13-octadecadienoic acid isomers is less than 5%, which embraces the instantly claimed percentage of 1%.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 8-9, 11-12, 14-15, 17-18, 20-21 and 23-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,333,353. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented invention is directed to a

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composition comprising 92% of t10, c12 isomer of conjugated linoleic acid which overlaps with the composition of isomerized conjugated linoleic acid comprising at least 50% c9,t11-octadecadienoic acid and t10,c12-octadecadienoic acid as claimed in the instant application.

In looking in continuity data, it is noted that applicant has numerous patents encompassing the same or similar subject matter of the instant application, for example, claims 1-20 of US Patent 6,465,666. Applicant should review all subject matter considered the same or similar and submit the appropriate Terminal Disclaimer(s).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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